

February 9, 2005



Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**RE: Docket No. 2005N-0036:
Use of Color on Pharmaceutical Product Labels,
Labeling and Packaging;
Public Hearing**

Dear Sir/Madam:

This letter serves as notice of Novo Nordisk's intent to participate in the referenced part 15 Public Hearing concerning the use of color on pharmaceutical product labels.

Presenter's information:

- Name: Mary Ann McElligott, Ph.D.
- Address: Novo Nordisk Inc., 100 College Road West, Princeton, NJ 08540
- Telephone number: 609-987-5831
- Affiliation: Associate Vice President, Regulatory Affairs, Novo Nordisk Inc.
- Time requested: 30 minutes

Summary of presentation:

Novo Nordisk gained FDA approval to use color branding on our insulin analogue packaging on October 8, 2004. During this presentation we will outline the multiple factors that led to our request for this approval, cover the past and present regulatory environment for the addition of color to insulin products. In addition, we will speak to the potential risks and benefits of using color on drug packaging to enhance public safety.

Novo Nordisk believes that our presentation will address in part the issues outlined in the Federal Register notice for this public hearing by providing our viewpoint on the third bulleted question under the Scope of the Hearing.

Sincerely,

Novo Nordisk Inc.

John [Signature] for Mary Ann McElligott

Mary Ann McElligott, Ph.D.
Associate Vice President,
Regulatory Affairs

APE

2005N-0036

Novo Nordisk Inc.
100 College Road West
Princeton, NJ 08540